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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,855	11/29/2001	Jerome Segal	70802.01	6694

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EXAMINER	
STIGELL, THEODORE J	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,855	SEGAL ET AL.	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,32,35-39,45-68 and 85-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *39* is/are allowed.

6)☐ Claim(s) *31,32,35-38,45-68 and 85-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/08/2006 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-32, 46-47, 53, and 61 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Brown, III et al. (6,219,577). Brown discloses an iontophoresis, electroporation and combination catheter for local drug delivery to arteries and other body tissues, comprising, a catheter (1O) having distal end (14), a proximal end (12),

and an iontophoretic transport means (24), the catheter having one lumen (see Figure 3) or more lumens (see Figure 4); a cylindrically shaped expansion member (20) coated or impregnated with a drug or other therapeutic agent positioned on the distal end of the catheter, an inner flow passage (78) positioned between the catheter and cylindrically shaped expansion member, wherein the inner flow passage can allow fluid to flow through the expansion member, the cylindrically shaped expansion member having a first contracted diameter (see Figure 1) and a second expanded diameter (see Figure 2), the second expanded diameter being larger than the first contracted diameter; see Column 8, lines 13-27, Column 9, lines 1-26; Column 1 O, lines 13-17 and lines 35-68; Column 11, lines 22-63; Column 14, lines 17-68; and Column 15, lines 1-22 and lines 62-63.

Claims 31 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Feiring (5,236,413). Feiring discloses a mechanical dilation and medicament delivery device comprising a catheter (10) having a proximal and distal end and an iontophoretic means (36), the catheter have one or more lumens, a cylindrically shaped extension member (14) positioned on the distal end of the catheter adapted to dilate an obstruction, the expansion member having a first contracted diameter and a second expanded diameter, the second diameter being larger than the first diameter, an inner flow passage (24) positioned between the catheter and the member, and the device being adapted to dilate the vessel, expose an obstruction to a medicament, while the inner flow passage allows fluid to flow through the expansion member.

Claims 35-38, 64-68, and 85-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian (5,304,121). Sahatjian discloses a method for dilating and delivering a medicament to an obstruction in a body passageway comprising the steps of advancing a mechanical dilatation catheter (3) to a predetermined site within a body passageway, said catheter having a cylindrically shaped expansion member (4) having at least portions of a proximal end, a middle portion, and a distal end coated with a medicament and an iontophoretic transport means (43), said cylindrically shaped expansion member being moveable between a first contracted configuration wherein said member is defined by a first dimension extending in a radial direction, and a second expanded configuration wherein said expansion member is defined by a second dimension extending in said radial direction, applying a force on said cylindrically shaped expansion member in an axial direction to move said expansion member between said first contracted configuration to said second expanded configuration wherein said obstruction is dilated, and operating said iontophoretic means to deliver said medicament into said obstruction or body passageway, which further comprises the step of positioning a guidewire in the body passageway, and wherein said advancing step is accomplished by threading said catheter over said guidewire, and further comprising the steps of varying the electric current.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,219,577 B1) in view of Dubrul et al. (US 6,450,989 A).

Brown, 111 et al. discloses the invention as claimed with the exception of the cylindrically shaped expansion member comprising a first plurality of flexible elongate elements helically wound in a first direction or rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

Dubrul et al. discloses a dilating and support apparatus comprising a dilation mechanism (9), as depicted in Figures 4-A and 4-B, made of an open, mesh metal braid, which allows for perfusion therethrough and is formed by a "Maypole" dance of filament carriers to create a zigzag pattern, wherein one filament moves helically clockwise and the other moves helically counter-clockwise, see Column 13, line 35 through Column 14, line 28; Column 17, lines 30-31; and Column 21, line 4 through Column 22, line 55.

It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with an open, mesh braid as taught by Dubrul et al. so as to increase the amount of surface area of the device in contact with the vessel wall thereby enabling more controlled and accurate delivery of medicament to affected wall tissue.

Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,219,577 B1) in view of Segal (US 5,527,282 A). Brown, 111 et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like. Segal discloses a vascular dilatation device for localized delivery of heparin, TPA, hirudin, or various anti-thrombin agents, see Column 10, lines 55-61. It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s catheter for local drug delivery with heparin delivery as taught by Segal, so as to prevent clotting of the blood adjacent the dilation device.

Claims 50-52, 54-58, 62, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,2 19,577 B 1) in view of Lennox (US 6,280,411 B1), Palasis et al. (US 6,369,039 B1), or Naimark et al. (US 6,638,246 B1).

Brown, 111 et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 50-52, 54-58, 62 and 63.

Lennox (Column 4, line 22 through Column 5, line 35), Palasis et al. (Column 4, line 64 through Column 6, line 22), and Naimark et al. (Column 8, line 50 through

Column 10, line 23), all individually, discloses a device for localized delivery of drug agents comprising an expansion member (210, 120, 10/20N208/30/40N408/50/60/80A/80B, respectively) coated with a medicament comprising a promoter of vascular cell growth, a transcriptional activator, an inhibitor of vascular cell growth, a growth factor receptor antagonist, a cholesterol-lowering agents, a vasodilating agent, an agent that interferes with endogenous vasoactive mechanisms, estrogen, a smooth muscle inhibitor, a compound that inhibits cellular proliferation, and paclitaxel.

It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Lennox, Palasis et al. or Naimark et al., so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

Claims 59, 60, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 111 et al. (US 6,2 19,577 B1) in view of Hanson et al. (US 5,985,307A). Brown, 111 et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 59, 60, 80 and 81.

Hanson et al. (Column 18, line 50 through Column 19, line 339 and Column 26, line 62 through Column 27, line 3) discloses a device for localized delivery of drug agents comprising an expansion member (50) containing a medicament comprising an

agent that modulates intracellular calcium binding proteins, and a receptor blocker for contractile agonists.

It would have been obvious to one having ordinary skill in the art to have modified Brown, 111 et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Hanson et al., so as to enable treatment of a variety of conditions including localized disease and/of vessel occlusion.

Allowable Subject Matter

Claim 39 is allowed.

Response to Arguments

Applicant's arguments filed 11/08/2006 have been fully considered but they are not persuasive. In response to the Applicant's argument that Brown '577 does not disclose an inner flow passage to allow blood or other bodily fluids to flow through the expandable member, the Examiner respectfully disagrees. The lumen (78) would allow fluid to flow through the expansion member if fluid was directed into lumen (78).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Theodore J. Stigell

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